

## Claims

1. A pharmaceutical composition comprising:

i) a controlled release formulation of 3'-azido-3'-deoxythymidine or a pharmaceutically acceptable derivative thereof; and

5 ii) an immediate release formulation of 3'-azido-3'-deoxythymidine or a pharmaceutically acceptable derivative thereof and (2R,cis)-4-amino-1-(2-hydroxymethyl-1,3-oxathiolan-5-yl)-(1H)-pyrimidin-2-one or a pharmaceutically acceptable derivative thereof.

2. A pharmaceutical composition comprising:

10 i) one layer containing a controlled release formulation of 3'-azido-3'-deoxythymidine or a pharmaceutically acceptable derivative thereof; and

15 ii) a second layer containing an immediate release formulation of (2R,cis)-4-amino-1-(2-hydroxymethyl-1,3-oxathiolan-5-yl)-(1H)-pyrimidin-2-one or a pharmaceutically acceptable derivative thereof and 3'-azido-3'-deoxythymidine or a pharmaceutically acceptable derivative thereof.

3. A pharmaceutical composition according to claim 1 or 2 wherein the controlled release formulation releases 3'-azido-3'-deoxythymidine within 3 - 6 hours.

20 4. A pharmaceutical composition according to any of claims 1 - 3 wherein the controlled release formulation comprises a mixture of polymers.

5. A pharmaceutical composition according to claim 4 wherein the polymers are hydroxypropylmethylcellulose.

6. A pharmaceutical composition according any of claims 1 - 5 wherein the amount of (2R,cis)-4-amino-1-(2-hydroxymethyl-1,3-oxathiolan-5-yl)-(1H)-pyrimidin-2-one is from about 150 to about 450 mg per unit dosage form.
- 5 7. A pharmaceutical composition according any of claims 1 - 5 wherein the amount of 3'-azido-3'-deoxythymidine is from about 100 to about 750 mg per unit dosage form.
8. The pharmaceutical composition according to any of claims 1 - 6 wherein (2R,cis)-4-amino-1-(2-hydroxymethyl-1,3-oxathiolan-5-yl)-(1H)-pyrimidin-2-one is provided substantially free of the corresponding (+)-enantiomer.
- 10 9. The pharmaceutical composition according to any of claims 1 - 6 wherein (2R,cis)-4-amino-1-(2-hydroxymethyl-1,3-oxathiolan-5-yl)-(1H)-pyrimidin-2-one is provided such that the corresponding (+)-enantiomer is present in an amount of not more than about 5% w/w of the amount of (2R,cis)-4-amino-1-(2-hydroxymethyl-1,3-oxathiolan-5-yl)-(1H)-pyrimidin-2-one.
- 15 10. A pharmaceutical composition according to any of claims 1 - 9 for once daily administration.
11. A pharmaceutical composition according to any of claims 1 - 9 in the form of a bilayer tablet or multilayer tablet.
12. A pharmaceutical composition according to any of claims 1 - 9 in the form of a bilayer tablet.
- 20 13. A pharmaceutical composition according to any of claims 1 - 9 in the form of a tablet within a tablet.
14. A method for the treatment or prevention of an HIV infection in a mammal comprising administering a pharmaceutical composition according to any of claims 1 - 13.